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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,004

Applicant(s)

BRESLAUER ET AL.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

Following entry the amendment filed 7/24/2003, claims 46-49 are pending.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/25/2003 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 47-49 recite the limitation " multiple initial nucleic acid duplexes" in claim 47.

There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 46 is rejected under 35 U.S.C. 102(b) as being anticipated by Heller (5,532,129, issued July 2, 1996).

Heller discloses measuring changes in FET donor or acceptor intensity of a nucleic acid duplex comprising a first nucleic acid strand labeled with a donor of a FET pair and a second nucleic acid strand labeled with an acceptor of the FET pair in the presence of a target nucleic acid (See column 4, lines 18-37). Thus, the teachings of Heller anticipate the limitations of claim 46.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller (5,532,129, issued July 2, 1996) as applied to claim 46, further in view of Chan (6,210,896, issued April 3, 2001).

The teachings of Heller are set forth in section 5 above. Heller additionally discloses the arrangements of multiple donors groups transferring energy to a single or smaller number of acceptor groups (See column 8, lines 46-51).

Heller does not disclose distinguishably labeled initial nucleic acid duplex, and that the changes can be monitored via selective fluorescence excitation with different wavelength, first nucleic acid strands of each nucleic acid duplex are labeled with the same FET donor and the second nucleic acid strands are labeled with different FET acceptor.

Chan disclose a method for linear analysis of polymers (See column 2, lines 24-26). The polymers are nucleic acid sequences (See column 3, lines 27-22) are labeled with a fluorophore (See column 3, lines 33-40 and column 9, lines 63-65). The method is performed on a plurality of polymers simultaneously (See column 4, lines 8-9). Different labels can be used to label different polymer (See column 5, lines 50-53). A plurality of molecular motors is tethered to the support in an organized array (See column 3, lines 42-44). The molecular motors can be DNA polymerase or peptides (See column 3, lines 51-55). The DNA polymerase is labeled with several fluorescent molecules e.g. donor fluorophore and the nucleic acid is labeled with an acceptor fluorophore (See column 9, lines 16-21). As the acceptor fluorophore moves past the donor fluorophore, fluorescence resonance energy transfer occurs (See column 9, lines 21-23). Or the nucleic acid is labeled with donor fluorescence as opposed to the acceptor (See column 12, lines 14-25). The sample may be labeled with different wavelength fluorophore. Each of the fluorophores can be detected separately to provide distinct readings from the same sample (See column 24, lines 19-33).

One ordinary skill in the art at the time of the instant invention would have been motivated to modify the method of Heller by using either donor fluorophore or acceptor fluorophore at different wavelength for screening nucleic acid duplex stability. The motivation is that different wavelength can be detected to provide information about different labels (See column 24, lines 32-33) in which the structural information about the polymer is determined based upon the linear analysis on the polymer (See column 6, lines 42-44) and multiple samples could be analysed simultaneously with different fluorophores in which more accurate and rapid information is provided (See column 24, 19-24). Although in the method of Chan, the duplex is formed by polymerase and nucleic acid, the polymerase is labeled with either donor or acceptor fluorophore and nucleic acid is labeled with either donor or acceptor fluorophore, the concept of that either multiple donor fluorophore or acceptor fluorophore detected at different wavelength was disclosed. Thus, it would have been prima facie to apply different wavelength labels on the first strand of nucleic acid or the second strand of nucleic acid as either donor labels or acceptor labels with different wavelength of detection for screening the nucleic acid duplex stability.

Summary

8. No claims are allowable.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

November 10, 2003



ETHAN WHISENANT
PRIMARY EXAMINER